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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,102	09/21/2005	Takane Yokotagawa	053057	4675

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WASHINGTON, DC 20036

EXAMINER
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NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	Application No. 10/550,102	Applicant(s) YOKOTAGAWA ET AL.	
	Examiner Ronald T. Niebauer	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                         |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                             | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/26/06, 9/21/05</u> | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group I (claims 1-5,9) and species of sequence ID 1 in the reply filed on 2/5/07 is acknowledged. Applicant noted in the reply on 2/5/07 that claims 1,2,4,5, and 9 read on the elected species, but the Examiner believes a mistake was made in this determination since claims 4 and 5 do not read on SEQ ID NO:1. Claims 4 and 5 represent modified forms of SEQ ID NO:2, not SEQ ID NO:1 (for example pages 16-17 of specification). Hence, claims 1,2,3 and 9 read on the elected species.

Claims 4-8,10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/5/07.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 9 refer to 'an intermolecular bond between two of the cysteines'. Intermolecular means between two molecules, intramolecular means within a molecule.

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The wording of the claim implies that the bond forms between a single molecule which is not consistent with the common definition of intermolecular. No support is provided in the specification for intermolecular bonds. Figure 7 seems to imply intramolecular bonds. Applicant should clarify the claim. For purposes of examination, the claims will be examined as if the term intramolecular is used.

Claims 1-3 and dependent claim 9 refer to an amino acid sequence represented by a particular sequence, for example SEQ ID NO:1. In this context the meaning of 'represented by' is unclear. Does this mean only SEQ ID NO:1 or can it include variants of SEQ ID NO:1 as well. Does it include functionally similar peptides? For purposes of examination, the claims will be interpreted such that 'represented by' is broadly interpreted to include larger peptides that include SEQ ID NO:1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Section 2163 of the MPEP states:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species..... A "representative number of species" means that the species which are adequately described are representative of the entire genus.

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Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Claim 3 is drawn to a polypeptide of which one or several of the amino acids have been deleted, substituted, inserted or added. This claim is broad in scope and since the degree of deletion/substitution/insertion is not specified nearly any polypeptide could meet this claim limitation. A few examples of modified polypeptides have been provided in the specification (such as example 3) but due to the substantial variation possible a sufficient variety of species has not been provided. Since the genus is broad and a representative number of species has not been described the written description requirement has not been met. Further it is well known in the art that modifying a protein by a deletion/substitution/insertion can alter the proteins structure and function. For example Bowie et al. teach that for certain proteins no substitutions can be made at particular positions (page 1306 column 2 line 18). Hence, the tolerance to amino acid sequence variation is often unpredictable. Since claim 3 refers to disulfide bond formation and channel inhibiting activity, a more specific description of the protein structure and modified residues would be needed to predict the effects of modifications.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1,2,3 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a polypeptide

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which can be naturally occurring (for example in spider venom) and has not been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature. It would be remedial to amend the claim to recite 'an isolated polypeptide'.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Ostrow et al. (as cited in IDS).

Claim 2 recites a polypeptide represented by SEQ ID NO:1 not represented by SEQ ID NO:4. The claim has been interpreted such that 'represented by' is broadly interpreted to include larger peptides that include SEQ ID NO:1.

Ostrow et al. teach the GsMTx4 peptide (abstract line 1). Ostrow et al. teach that this protein is 'translated as a precursor protein of 80 amino acids' (2<sup>nd</sup> line of abstract, page 270 last paragraph line 1). This 80 amino acid peptide meets the limitations of claim 2 since it comprises SEQ ID NO:1 and does not solely consist of SEQ ID NO:4 as it includes additional residues. Further, the presence of cysteine residues allows for the

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formation of intramolecular disulfide bonds (page 263 last paragraph line 3, page 269 line 3).

Claims 1, 3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Oswald et al. (as cited in IDS).

Claim 1 recites a polypeptide represented by SEQ ID NO:1. Claim 3 recites a polypeptide represented by SEQ ID NO:1 in which one or several of the amino acids have been deleted/substituted/inserted. Claim 9 recites a channel inhibitor comprising a polypeptide described in one of the previous claims. The claims have been interpreted such that 'represented by' is broadly interpreted to include larger peptides that include SEQ ID NO:1.

Oswald et al. teach the GsMTx4 peptide (Figure 1). The GsMTx4 peptide meets the limitation of being represented by SEQ ID NO:1 since it includes SEQ ID NO:1 (Figure 1 of Oswald et al.). Oswald et al. teach GsMtx-2 (page 34443 last paragraph 2<sup>nd</sup> line; Figures 1 and 3). The amino acids of GsMtx-2 share some similarity with those of GsMtx-4 (Figure 1,3) but meet the limitation of having several amino acids deleted/substituted/inserted. Further, GsMtx-2 has intramolecular disulfide bonds (page 34447 line 7 and Figure 3) and is a mechano-sensitive channel inhibitor (page 34446 line 5 and figure 1). Hence all the limitations of the claims 1, 3 and 9 are taught by Oswald et al.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ZACHARIAH LUCAS  
PATENT EXAMINER